

Remarks

The Office Action dated June 11, 2009 has been reviewed. Claims 81-88, 89-97, and 99-100 were pending in the application. Independent claims 81 and 95 have been amended to more clearly recite the inventive concepts therein, and reformatted to improve clarity. Independent claim 101 has been added. Claims 90 and 99 have been amended to recite “wherein the attachment means is integral to the sleeve.” Applicant believes no fee is required by the addition of independent claim 101 because 3 independent and 19 total claims are now pending. For the reasons set forth below, the claims are in condition for allowance, and Applicant respectfully requests reconsideration and withdrawal of each and every objection and rejection.

I. Statement of Substance of Interview

Applicant thanks the Examiner for the courtesy of a telephonic interview with Applicant’s attorney on August 4, 2009. During the interview, the pending rejections under 35 U.S.C. § 103 were discussed, as well as proposed amendments. Applicant’s attorney argued that the claims are non-obvious over the combinations of the cited references at least because: (1) the proposed combinations of cited references would not include every element of the claims, and (2) the proposed modification of the Sabin reference is improper because it would render Sabin’s device unsuitable for its stated purpose. No agreement was reached on the patentability of the claims, but the Examiner indicated willingness to consider the arguments further in this response.

II. Amendments and Exemplary Support

Independent claims 81 and 95 have been amended to recite (and new independent claim 101 recites) “the sleeve configured such that when lengthened along a length of a tube between the first and second apertures within the sleeve, the sleeve will grip the tube to exert a compressive gripping force evenly distributed around the tube and along a length of the tube in the sleeve and will further lengthen in response to movement of the tube to increase the compressive gripping force, and when shortened the compressive gripping force will be released to permit the tube to move relative to the sleeve . . .” (emphasis added).

Independent claim 81 has been amended to recite (and new independent claim 101 recites) “attachment means configured to couple the sleeve to a patient.”

Independent claim 95 has been amended to recite “attachment means coupled to one of the first end and the second end of the sleeve and configured to couple the sleeve to a patient; and a ring coupled to the other of the first end and the second end of the sleeve and configured such that if the ring is moved toward the attachment means the sleeve will shorten, and if the ring is moved away from the attachment means the sleeve will lengthen, the ring surrounding the aperture in the end of the sleeve to which the ring is coupled.”

New independent claim 101 recites “attachment means coupled to one of the first end and the second end of the sleeve and configured to couple the sleeve to a patient; and a ring coupled to the other of the first end and the second end of the sleeve such that the ring holds open the aperture in the end to which the ring is coupled so the ring is operable to shorten the sleeve by moving the ring towards the attachment means.”

Applicant respectfully submits that the amendments add no new matter. Support for the amendments can be found throughout the application as-filed, for example, on page 7; page 13; and FIGS. 3-8.

III. Objections to the Specification and Claims under 35 U.S.C. § 112, sixth paragraph

The specification was objected to because the claims may have seemed to invoke means-plus-function language under 35 U.S.C. § 112. Applicants respectfully disagree. Nevertheless, independent claims 81 and 95 have been amended to recite (and new independent claim 101 recites) attachment means “configured to couple the sleeve to a patient.” Thus, the claims do not invoke 35 U.S.C. § 112, sixth paragraph, and Applicants respectfully request reconsideration and withdrawal of the objections to the specification and the claims.

IV. Claims 81-101 are Patentable over Sobin and Plass

Claims 81-100 under 35 U.S.C. §103(a) were rejected as being unpatentable over Sobin et al. (US 4,509,877) in view of Plass et al. (US 5,232,453). Applicant respectfully disagrees and traverses.

A. Any Combination of Sobin and Plass Would Not Include All of the Claimed Features

The Office Action stated that “when the sleeve 6 [of Sobin] is fully extended, the sleeve 6 is capable of gripping a tube to generate a compressive gripping force evenly distributed around

the tube and along the length of the tube such that the sleeve will further lengthen in response to movement of the tube to increase the compressive gripping force.” Office Action at p. 3. Applicant respectfully disagrees. Sabin is directed to a tapered torque strain relief coupling for “strain relief for the point of attachment of a flexible member to a rigid member.” *Abstract* (emphasis added). The *sleeve* of Sabin is directed to strain relief and is not configured to grip anything or to exert a compressive gripping force. For example, “the circumference of the braid itself is constant.” Col. 4, lines 51-52 (emphasis added). Additionally, there is simply no motivation for the sleeve of Sabin to grip anything because “[c]able 1 is *attached* to plug 3 by means of *clamp* 5 held by bolt 4.” Col. 4, lines 41-42 (emphasis added). Sabin *requires* a flexible member with a weave that *varies along its length*. For example, Sabin teaches that “the end of a flexible member, at its point of attachment to a rigid member, is enclosed within a plurality of braided strands . . . [that] are *very closely or narrowly woven* at the point of attachment, and *are more openly or widely woven* as the distance from the point of attachment increases.” Col. 3, lines 47-52 (emphasis added).

Independent claims 81 and 95, as amended, and new independent claim 101, recite a “sleeve configured such that when lengthened along a length of a tube between the first and second apertures within the sleeve, the sleeve will grip the tube to exert a compressive gripping force *evenly distributed* around the tube and *along a length of the tube in the sleeve . . .*, and when shortened the compressive gripping force will be released to permit the tube *to move relative to the sleeve*.” (emphasis added). The sleeve of Sabin is not capable of exerting a compressive gripping force *evenly distributed* along a length of a tube because the weave of Sabin is explicitly uneven. As a result, even if the sleeve of Sabin were lengthened in the manner suggested in the Office Action, Sabin’s sleeve would at most exert an uneven force along a length of a tube in the sleeve. In particular, the closely woven portions would exert a greater compressive force than the loosely woven portions of the sleeve. Applicants further submit that given its constant circumference, it is doubtful that Sabin’s sleeve could even be lengthened to exert a compressive gripping force. See Sabin, at col. 4, lines 51-52 (emphasis added). Additionally, because the “[c]able 1 is *attached* to plug 3 by means of *clamp* 5,” the cable 1 of Sabin is not capable of moving relative to the sleeve in the claimed fashion, regardless of how much the sleeve might be shortened. See Sabin, at col. 4, lines 41-42 (emphasis added).

Sobin's sleeve is not "configured such that when lengthened along a length of a tube between the first and second apertures of the sleeve, the sleeve will grip the tube to exert a compressive gripping force *evenly distributed* around the tube and *along a length of the tube in the sleeve*," as recited in the independent claims (emphasis added). Nor is Sobin's sleeve configured such that . . . when shortened the compressive gripping force will be released to permit the tube *to move relative to the sleeve*," as recited in the independent claims. Plass does not supply the deficiency. In particular, Plass is directed to coupling a catheter to a patient:

A catheter holder [with] a pad of medical grade adhesive material having one surface for attachment to the skin of a wearer, and a pair of tapes secured to and extending from the other surface of the pad. A multiple use adhesive is placed on a surface of at least one tape which surface faces generally towards the other tape. With such an arrangement, the two tapes can be stuck together to enclose the catheter and at the same time the tape carrying the adhesive sticks to the adjacent wall of the catheter so preventing longitudinal movement of the catheter relative to the pad.

Plass, at *Abstract*. Even if Sobin and Plass were combined, the sleeve of Sobin would not be configured in the claimed manner, and Plass contains no suggestion to modify the sleeve to do so. Therefore, no combination of Sobin and Plass could result in a fastener having all elements of the independent claims.

B. Any Modification of Sobin to Result in the Claimed Features Would Render Sobin Unsuitable for Its Intended Purpose and Would Change Sobin's Principle of Operation

Further, any proposed modification of Sobin to result in the claimed configuration is improper because it would render Sobin's device unsuitable for its stated purpose and would change Sobin's principle of operation. As the Office is aware, modification is improper if it would render the prior art unsuitable for its stated purpose. *See In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984); *see also* MPEP § 2143.03(V). As the Office is also aware, modification is improper if it would change the principle of operation of the prior art reference. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959); *see also* MPEP § 2143.03(VI).

Any proposed modification of Sobin's sleeve to result in the presently claimed configuration would render Sobin's sleeve unsuitable for its stated purpose. Sobin's sleeve is designed, and the weave purposefully uneven, so that "[t]he stress, and its resulting strain, are thereby *tapered* from the point of connection with the rigid member over the length of the braid

and the flexible member." Sabin, at col. 5, line 68 – col. 6, line 3. If the sleeve of Sabin were modified to be braided evenly, it would render it unsuitable for *tapering* the stress and strain in the cable 1. Additionally, in Sabin, "[c]able 1 is *attached* to plug 3 by means of *clamp 5*," such that Sabin's sleeve relieves strain at a fixed point of attachment. Col. 4, lines 41-42 (emphasis added). Any modification of Sabin's sleeve such that "when shortened the compressive gripping force will be released to permit the tube to move relative to the sleeve," as presently claimed, would render Sabin's sleeve unsuitable for relieving strain at a fixed point of attachment because the point of attachment would no longer be fixed. Modification of Sabin that could result in the claimed sleeve configuration is therefore improper because it would render Sabin's sleeve unsuitable for its stated purpose.

Any proposed modification of Sabin's sleeve to result in the presently claimed configuration would change the principle of operation of Sabin. Sabin's sleeve is provided configured with an uneven braid such that the "spacing between adjacent strands . . . [varies] as a function of the distance between [a] point and the point of attachment." Sabin, at col. 4, lines 47-50 and FIGS. 1-2. As noted above, Sabin's sleeve has a weave that is purposefully uneven so that "[t]he stress, and its resulting strain, are thereby *tapered* from the point of connection with the rigid member over the length of the braid and the flexible member." See Sabin, at col. 5, line 68 – col. 6, line 3. Given Sabin's explicit teaching of an uneven braid, *any* modification that results in an even braid will change the principle of operation. Further, even if Sabin's sleeve were modified to have an even braid *and* reduce strain, it would still change the principle of operation because it would no longer *taper* stress and strain along the length of the sleeve. Any modification of Sabin that would result in an even braid is therefore improper because it would render Sabin's sleeve unsuitable for its stated purpose and would change Sabin's principle of operation.

Further, even if Sabin were combined with Plass, the flexible nature of Plass's tapes would undermine the rigid nature of the "point of attachment of a flexible member to a rigid member." Sabin, at *Abstract*. As such, modification of the primary Sabin reference is improper because it would render Sabin unsuitable for its stated purpose and would change Sabin's principle of operation.

Because no combination of Sabin and Plass would include all elements of the claims, and any modification of Sabin to include all elements of the claims would be improper, independent claims 81, 95, and 101 are non-obvious and patentable over Sabin and Plass. Additionally, because claims 82-87, 89-94, 96-97, and 99-100 depend from claims 81 and 95, they are also non-obvious and patentable. *See In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *see also* MPEP § 2143.03. Applicant therefore requests reconsideration and withdrawal of the rejection of claims 81-100 under 35 U.S.C. § 103 over Sabin in view of Plass.

V. Claims 81-101 are Patentable over Lewis In View of Bowen or Delk

Claims 81-100 under 35 U.S.C. §103(a) were rejected as being unpatentable over Lewis (US 3,122,806) in view of Bowen et al. (US 5,147,322) or Delk et al. (US 5,292,312). Applicant respectfully disagrees and traverses.

A. There is No Motivation to Combine Lewis and Bowen or Lewis and Delk

The Office Action stated that “a catheter tube is analogous in structure to a cable line . . . the cable line and the tube are interchangeable and can be used in the medical arts as it relates with the tube . . . the gripping device of Lewis is capable of applying for securing medical tubes.” Office Action at p. 5. Applicant respectfully disagrees.

Lewis is directed to a “gripping device.” *Title*. Lewis does not recite or suggest *any* medical uses or applications. Rather, Lewis suggests a number of non-medical uses, such as, for example, to “pull lines over sheaves, crown blocks or traveling blocks used on *drilling rigs in oil fields* and the like . . . pulling electrical wire or wires through conduits and the like.” Col. 1, lines 15-20. Nothing in Lewis would suggest a medical use. In fact, the teachings of Lewis suggest that the cable- or wire-pulling uses of Lewis are not analogous to medical-tube uses. For example, Lewis discusses at length “sharp edges where the cable is cut . . . [and] electrical cables are field cut before pulling, leaving sharp cutting edges.” Col. 1, lines 25-31. As would be apparent to one of ordinary skill in the relevant medical arts, these characteristics described by Lewis are not analogous to medical tubing.

Nor do Delk or Bowen appear to include any suggestion that either could or should be combined with any *additional* gripping device. Rather, each includes its own securing or holding structure. For example, Bowen discloses a “medical appliance securing device,” Bowen,

at *Abstract*, and Delk discloses a “medical conduit holder for securing medical conduits to the skin of a patient,” Delk, at *Abstract*. As such, a person of ordinary skill in the art would not be motivated to *combine* the gripping device of Lewis with the teachings of either Bowen or Delk.

B. Any Combination of Lewis and Bowen or Lewis and Delk Would Not Include All of the Claimed Features

Independent claim 81 recites “a sterile tubular sleeve . . . and attachment means configured to couple *the sleeve to a patient*” (emphasis added). Even if the teachings of Lewis were combined with the teachings of Bowen or Delk, it would not result in a fastener comprising a *sterile* tubular sleeve *and* attachment means configured to couple *the sleeve to a patient*, as recited in independent claim 81. The securing devices of Bowen and Delk are explicitly intended for securing medical appliances such as tubular members to a patient. Applicant is unable to locate any teaching in Lewis, Bowen, or Delk that would suggest to a person of ordinary skill in the relevant medical art that the securing devices of Bowen or Delk could be used to couple the *sleeve of Lewis to a patient*. If the figures of the present application are relied upon to suggest that that the securing devices of Bowen or Delk could be coupled to the “loop or eye 8” of Lewis, then such reliance would be *impermissible hindsight*. See MPEP § 2141.01(III) (“The requirement ‘at the time the invention was made’ is to avoid impermissible hindsight.”); see also *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984) (“It is difficult but necessary that the decisionmaker forget what he or she has been taught . . . about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the . . . art.”). As such, the combination of Lewis with Bowen or Delk would not result in “a sterile tubular sleeve . . . and attachment means configured to couple *the sleeve to a patient*,” as recited in claim 81 (emphasis added).

Independent claim 95 recites “attachment means coupled to *one of* the first end and the second end of the sleeve and configured to couple the sleeve to a patient; and *a ring* coupled to *the other of* the first end and the second end of the sleeve . . . *the ring surrounding the aperture* [“through which a tube can pass”] in the end of the sleeve to which the ring is coupled.” Even if the securing devices of Bowen or Delk were coupled to the eye 8 of Lewis, there is nothing in any of the references to suggest a ring surrounding the aperture in the *other end* (article-receiving

end 3) of Lewis's gripping device. In fact any modification of Lewis to include such a ring would be counterintuitive (non-obvious) and would render the Lewis device unsuitable for its stated purpose. *See In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984); *see also* MPEP § 2143.03(V). For example, Lewis describes that its device is "compressed longitudinally to *increase its diameter* whereby an article 4 can be inserted into the article-receiving end 3." Col. 3, lines 66-68 (emphasis added). To enable this function, individual strands 7 are separately "joined together by connectors 9 such as metal members crimped thereon, soldered, or otherwise suitably secured thereto." Col. 3, lines 5-8. Importantly, and as illustrated in Lewis's figures, only two adjacent strands 7 are joined by each connector 9 such that the diameter of article-receiving end 3 can *increase* as necessary to receive an article. The addition of a ring as recited in claim 95 would be counterintuitive (non-obvious) and would likely render Lewis's gripping device unsuitable for its stated purpose because it would restrict the *increase* of the diameter of Lewis's article-receiving end 3.

Independent claim 101 recites "attachment means coupled to *one of* the first end and the second end of the sleeve and configured to couple the sleeve to a patient; and a ring coupled to *the other of* the first end and the second end of the sleeve such that the ring *holds open* the aperture in the end to which the ring is coupled so the ring is operable to shorten the sleeve by moving the ring towards the attachment means. Even if the securing devices of Bowen or Delk were coupled to the eye 8 of Lewis, there is nothing in any of the references to suggest a ring surrounding the aperture in the *other end* (article-receiving end 3) of Lewis's gripping device. In fact any modification of Lewis to include such a ring would be counterintuitive (non-obvious) and would render the Lewis device unsuitable for its stated purpose. *See In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984); *see also* MPEP § 2143.03(V). For example, Lewis describes the "article-receiving end 3" as "compressed longitudinally to *increase its diameter* whereby an article 4 can be inserted into the article-receiving end 3." Col. 3, lines 66-68 (emphasis added). As explained above for claim 95, the addition of a ring as recited in claim 95 would be counterintuitive (non-obvious) and would likely render Lewis's gripping device unsuitable for its stated purpose because it would restrict the *increase* of the diameter of Lewis's article-receiving end 3. Lewis further describes that "pull tends to extend the body portion longitudinally and thereby provide a contraction radially to *reduce the diameter* in the body

portion." Col. 3, line 73 – col. 4, line 1. As such, coupling a ring to the article-receiving end 3 of Lewis such that the ring *holds open* the article-receiving end 3 would be counterintuitive (non-obvious) because it would restrict the reduction in diameter described by Lewis.

Because there is no motivation to combine Lewis with Bowen or Delk without the use of impermissible hindsight, no combination of Lewis and Bowen or Delk would include every element of independent claims 81, 95, or 101, and any modification of Lewis to include all claimed elements would be counterintuitive (non-obvious) and/or would render Lewis's gripping device unsuitable for its stated purpose, independent claims 81, 95, and 101 are non-obvious and patentable over Lewis in view of Bowen or Delk. Additionally, because claims 82-87, 89-94, 96-97, and 99-100 depend from claims 81 and 95, they are also non-obvious and patentable. *See In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *see also* MPEP § 2143.03. Applicant therefore requests reconsideration and withdrawal of the rejection of claims 81-100 under 35 U.S.C. § 103 over Lewis in view of Bowen or Delk.

Conclusion

The foregoing is intended to be a complete response to the Office Action dated June 11, 2009. In view of the foregoing, Applicant respectfully submits that claims 81-101 are in condition for allowance, and respectfully requests reconsideration and withdrawal of the rejections, and prompt allowance of the claims.

The Examiner is invited to contact Applicant's agent at (512) 536-3083 with any comments or questions in order to expedite the resolution of any remaining issues.

Respectfully submitted,



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